

**VIRGINIA BOARD OF PHARMACY  
MINUTES OF BOARD MEETING**

Tuesday, April 13, 2004  
Fifth Floor  
Conference Room 2

Department of Health Professions  
6603 West Broad Street  
Richmond, Virginia 23230

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**CALL TO ORDER:** A meeting of the Board of Pharmacy was called to order at 12:45 p.m.

**PRESIDING:** Mark A. Szalwinski, Chairman

**MEMBERS PRESENT:** Kimberly A. Anderson  
Michael J. Ayotte  
John O. Beckner  
Willie Brown  
Carthan F. Currin, Jr.  
Michelle R. Easton  
Bobby Ison  
Mark A. Oley  
Leo H. Ross

**STAFF PRESENT:** Elizabeth Scott Russell, Executive Director  
Cathy M. Reiniers-Day, Deputy Executive Director  
Ralph A. Orr, Deputy Executive Director  
Elaine J. Yeatts, Senior Regulatory Analyst  
Howard M. Casway, Senior Assistant Attorney General  
Donna M. Lee, Administrative Assistant

**QUORUM:** With ten members of the Board present, a quorum was established.

**APPROVAL OF AGENDA:** Mr. Currin moved, and the Board voted unanimously to approve the agenda as presented.

**PUBLIC COMMENTS:** No public comments were received.

**APPROVAL OF MINUTES:** Mr. Szalwinski called for changes or corrections to the Minutes of January 14, 2004. Hearing no changes, the Minutes were approved as presented.

**REVIEW AND RESPONSE  
TO PUBLIC COMMENT  
ON PROPOSED  
REGULATIONS AND  
ADOPTION OF FINAL  
REGULATIONS:** Ms. Russell reviewed with the Board a draft of responses to a summary of written comments received on proposed regulations. Mr. Ayotte moved, and the Board voted unanimously, to adopt the draft as amended. (Attachment 1)

In response to a comment received that blood is not considered a

drug and should not be included in items under control of a pharmacy, Mr. Ayotte moved, and the Board voted unanimously, to change the wording of 18 VAC 110-20-440 D(6) to read as follows: "Blood components and derivatives, and synthetic blood components and products that are classified as prescription drugs."

After further review and discussion that attending physicians have their own DEA numbers and should not be using the hospital DEA numbers, Mr. Ayotte moved, and the Board voted unanimously, to delete the words "attending physician" in 18 VAC 110-20-510.

Mr. Beckner moved, and the Board voted unanimously, to adopt the proposed regulations as amended by the Board. (Attachment 2)

**LEGISLATIVE UPDATE:**

Ms. Yeatts reviewed and discussed with the Board an update on legislation that was passed by the 2004 General Assembly. The Board addressed certain agenda items not in the listed order relating to legislation as part of the legislative update.

**DISCUSSION OF DRAFT  
REGULATION FOR  
EXEMPT ACTION TO  
CONFORM TO HB783:**

HB783 was passed at the request of the Division of Forensic Science that was seeking the same exception in state law that is provided in federal law which would not require inventories of certain quantities of controlled substances used for standards. The bill requires the Board of Pharmacy to promulgate rules to implement the statute. Because the amendment is merely to conform regulation to statute, it can be handled under an exemption from the APA. The Board reviewed a draft amendment. Mr. Ross moved, and the Board voted unanimously, to delete the word "small" in the draft amendment to 18 VAC 110-20-720(5), and to adopt the draft as amended by the Board. (Attachment 3)

**HB856-APPOINTMENT TO  
THE THERAPEUTIC  
PHARMACEUTICAL  
AGENTS (TPA)  
FORMULARY  
COMMITTEE:**

In response to HB856, the Board of Optometry requested that the Board of Pharmacy appoint a representative to serve on the TPA Formulary Committee. After discussion of possible candidates, Mr. Oley moved, and the Board voted unanimously, to appoint Ralph Small, VCU School of Pharmacy, to this Committee.

**DISCUSSION OF  
EMERGENCY  
REGULATIONS TO  
IMPLEMENT HB577,  
DISCIPLINARY**

Ms. Yeatts informed the Board that the Department is working on draft regulations to implement HB577 and that the Board will need to adopt emergency regulations at the June 8<sup>th</sup> Board meeting. Ms. Russell stated to the Board that the Regulations Committee will review the draft regulations and make a recommendation to the

**PROCESSES:**

Board at the June 8<sup>th</sup> meeting.

Mr. Szalwinski changed the order of the agenda to discuss the topic: Request from Giant concerning faxing prescriptions for information purposes by patients.

**REQUEST FROM GIANT  
CONCERNING FAXING  
PRESCRIPTIONS FOR  
INFORMATION  
PURPOSES BY PATIENTS:**

The Board reviewed the email from Giant concerning its practice of allowing patients to fax their prescription to the pharmacy for information purposes for the pharmacist to use to prepare the prescription and have it ready for the patient when they arrive. According to Giant's email, the pharmacist would receive the original prescription from the patient and verify the prescription before the drug is given to the patient. The Board discussed concerns about the possibility of errors and abuse that may occur with this practice.

Mr. Oley moved, and the Board voted unanimously, to deny the request by Giant to allow patients to fax prescriptions as it does not conform to 18 VAC 110-20-280 that specifies that a prescription may only be faxed from a prescriber's practice location directly to the pharmacy.

**REVIEW OF NEW  
GUIDANCE DOCUMENT  
ON PRESCRIPTIONS:**

Ms. Russell reviewed and discussed with the Board the draft guidance document pertaining to Virginia Prescription Blank Requirements. Mr. Beckner moved, and the Board voted unanimously, to adopt the draft guidance document as amended by the Board on Virginia Prescription Blank Requirements. (Attachment 4)

**DISCUSSION OF USP-NF  
CHAPTER 797 STERILE  
COMPOUNDING:**

Facilities that perform sterile compounding have asked if the Board will begin enforcing standards of USP-NF Chapter 797 when it becomes effective on July 1, 2004. The Board established a subcommittee to review the standards of USP-NF Chapter 797 along with the current compounding laws, and to present a preliminary recommendation to the Board at its June 8<sup>th</sup> Board meeting. Mr. Ayotte, Mr. Currin, Mr. Ison, and Mr. Johnson, Deputy Director for Enforcement, were appointed to the subcommittee, with Mr. Orr staffing the subcommittee.

**DISCUSSION OF  
METHADONE CLINICS  
BEING LICENSED AS  
SPECIAL-USE  
PHARMACIES INSTEAD  
OF HAVING A**

Ms. Russell discussed the problems with methadone clinics not fitting well into any category of licensure of the Board of Pharmacy. She informed the Board that, prior to approximately five years ago, methadone clinics were licensed as special-use pharmacies. About five years ago, based on the practices at that time, where most of the methadone was being administered on-site

**CONTROLLED  
SUBSTANCE  
REGISTRATION  
CERTIFICATE:**

by nurses, and pharmacists were only present a couple of hours a week to package "take-home" doses, the Board converted these pharmacies to controlled substances registration certificates (CSRCs). This type of certificate more closely fit the practice than the pharmacy permit. Now, because of changes in federal treatment rules that allow greater flexibility in "take-home" doses, up to a 30-day supply, much more dispensing is being done. Staff of the Department of Health Professions met recently with staff of the Department of Mental Health, Mental Retardation, and Substance Abuse Services (DMHMRSAS) to discuss whether these facilities that were licensed by at least two federal agencies and also DMHMRSAS, really needed a license from the Board of Pharmacy. This is currently required in DMHMRSAS rules. The meeting was to consider how best to license these operations or whether the Board might want to petition DMHMRSAS to remove the requirement for regulation by the Board of Pharmacy altogether. Staff of DMHMRSAS at the meeting requested that the Board of Pharmacy regulate these facilities because their main focus is treatment, and because they do not have the expertise to regulate the drug security and accountability aspect of these operations. They reported that DEA does not conduct routine inspections or audits. After discussion at that meeting, staff determined that because of the dispensing being done at these operations, they better fit the model of either a pharmacy, where a pharmacist dispenses, or a physician dispensing license, where the physician dispenses the take-home doses. Based on the outcome of this staff meeting, Ms. Russell requested permission from the Board to change these operations from CSRCs back to special-use pharmacies or to physician dispensing licenses depending on the preference of the operation as to who would handle dispensing.

Mr. Ayotte moved, and the Board voted unanimously, to license methadone clinics as special-use pharmacies.

**DISCUSSION OF REFILL  
AUTHORIZATION  
REQUESTS:**

Ms. Russell reviewed with the Board correspondence that was received concerning standardization of refill requests by pharmacies. She said the main concern appeared to be that there was no standard format or conformity used for the refill requests. Ms. Russell stated to the Board that she did respond by informing the concerned parties that they could petition the Board to promulgate regulations regarding this matter and she provided them with a blank petition form for completion, however, she has not received a petition for rulemaking. The Board took no action in this matter.

**DEA PHARMACY THEFT  
PREVENTION PROGRAM:**

Ms. Russell provided the Board with brochures that she and staff from the Enforcement Division received from a meeting with DEA that contains information on theft prevention in pharmacies. She stated to the Board that DEA would like the Board's approval to allow the inspectors to distribute these brochures to pharmacies when they conduct inspections. The Board recommended that a letter be sent to corporations to inform them that a brochure will be distributed to pharmacies in the near future regarding theft prevention.

Mr. Beckner moved, and the Board voted unanimously, that inspectors be allowed to distribute the brochures to pharmacies when they conduct inspections.

**EXECUTIVE DIRECTOR'S  
REPORT:**

Ms. Russell stated that the Regulations Committee will be scheduling a meeting before the June 8<sup>th</sup> Board meeting to discuss legislative proposals and other regulatory issues.

She reminded the Board that the NABP meeting will be held on April 24-27, 2004. She also informed the Board that currently there are 5,909 registered pharmacy technicians.

**NEW BUSINESS:**

Mr. Szalwinski addressed the Board concerning the Medicaid P&T Committee and a request for guidance concerning monitoring of narcotics to prevent payment for overuse. Ms. Russell stated that she would look into how the Prescription Monitoring Program could be of use with this. The Board took no action at this time.

Ms. Russell stated to the Board that she will discuss the topic on the agenda pertaining to refill authorization requests of the prescriber prior to patient requesting refill at a later date when more information is available for consideration.

Ms. Easton moved, and the Board voted unanimously, that 18 VAC 110-20-90 B(1) be amended to change the words "American Council on Pharmaceutical Education" to read "Accreditation Council for Pharmacy Education" based on a recent name change by that organization.

**ADJOURN:**

With all business concluded, the meeting adjourned at 3:30 p.m.

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Donna M. Lee  
Administrative Assistant

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Elizabeth Scott Russell  
Executive Director

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Mark A. Szalwinski, Board Chair

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Date

Minutes  
Virginia Board of Pharmacy  
??Date??

ATTACHMENT 1